

## Precision water vapor permeability analysis of medical & pharmaceutical packaging

### Applications

Pharmaceutical packaging  
Bottles  
Pill containers  
Closures  
Surgical dressings  
Syringe products  
Bags  
Needles



Conforms to 21CFR Part 11

### Features & Benefits

- Analytical Systems Manufactured traceable to NIST.
- System validation with certified gas or film for speed and convenience.
- Absolute moisture measurement - No calibration required.
- Wide measurement range.
- Over 25 yrs experience of Proprietary Coulometric  $P_2O_5$  sensor.
- Flow, temperature and humidity control for ultimate responsiveness and repeatability.
- Intuitive Windows based software.
- No liquid coolants, catalysts or special gas mixtures required.

### Why measure permeability?

The measurement of permeation is often critical in medical and pharmaceutical applications:

- for protection
- to prevent contamination
- to extend the shelf life and potency of drugs
- to ensure powders do not clog

Permeability testing is used in the design and manufacture of blister packs, bottles, pill containers, surgical dressings, needles and syringe products.

Package integrity is necessary to maintain the quality of a drug product throughout its shelf life. Therefore the container and closure need to demonstrate their suitability to the product. The permeation of moisture through a package is a critical quality attribute for solid oral dosage forms, with moisture uptake being a common cause for product package failures.

The 7000 permeation analyzers can assist in fulfilling your medical and pharmaceutical packaging requirements.

## Manufacture traceable to NIST

All Systech Illinois analyzers are certified traceable to NIST. In addition, analytical performance is validated using NIST certified gases and NIST traceable films. A set of validation films and a spare P<sub>2</sub>O<sub>5</sub> sensor comes as standard with all of the water vapor permeation analyzers.

## P<sub>2</sub>O<sub>5</sub> Sensor Technology

The two most common sensor types for measuring moisture are IR (infra-red) and P<sub>2</sub>O<sub>5</sub> (phosphorous pentoxide). The P<sub>2</sub>O<sub>5</sub> sensor is more sensitive and stable than IR and does not require calibration. P<sub>2</sub>O<sub>5</sub> is the primary method for absolute moisture measurement. Illinois have over 25 years experience of using P<sub>2</sub>O<sub>5</sub> and IR sensor technology.

\*The Systech Illinois 7000 series analyzers comply with ASTM standard F-1249 with the exception of the sensor technology. The standard relates to an infrared sensor whilst the Systech Illinois analyzer uses a coulometric sensor - a dedicated method of moisture analysis.

## Wide measurement range

The 7000 series offer a wide measurement range providing research grade flexibility.

- Measurement range of 0.002-1000 g/m<sup>2</sup>/day with masking.
- Quality Assurance oriented speed and agility.
- Up to five expansion modules available to increase testing throughput.



## Precision control

These analyzers offer precision temperature and humidity flow control providing ultimate responsiveness and repeatability.

- Test gas and carrier flow gas controlled by premium electronic mass flow controllers.
- Accurate relative humidity range from 20% to 90%.
- Wide sample temperature range of 41 to 122°F (5 to 50°C).

## Laboratory Testing Services

Our test laboratory will perform your Permeation Testing Analysis. Whether you are developing innovative materials and packages or validating that your supplier is meeting specification. We can exceed your expectations with:

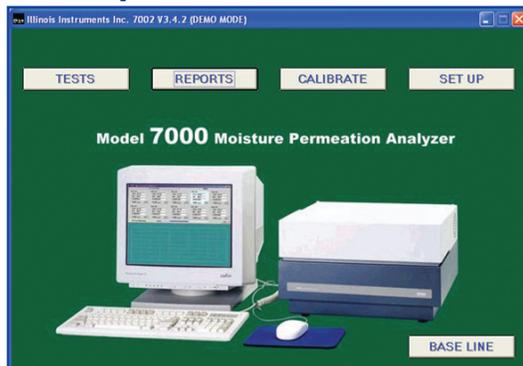
- Competitive Prices
- Independent non-biased results
- Fast Turnaround
- 25 Years Experience

## 21CFR Software

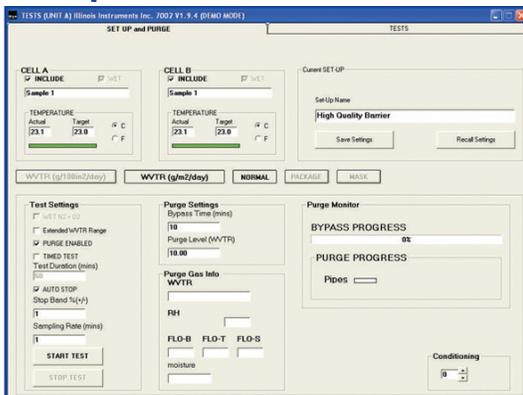
Used in conjunction with Microsoft® Windows.

- Password protected User Log-In.
- Test files are encrypted and cannot be altered.
- Audit files are created and encrypted recording date, time, user and action.
- Easy input and recall of operating parameters and test protocols.
- User-friendly data tracking, searches, sorts, storage and output capabilities.
- Graphical representation of measurement data in real time.
- Auto-stop feature stops test when samples have reached equilibrium or by user entered elapsed time value.
- Complete system diagnostics.

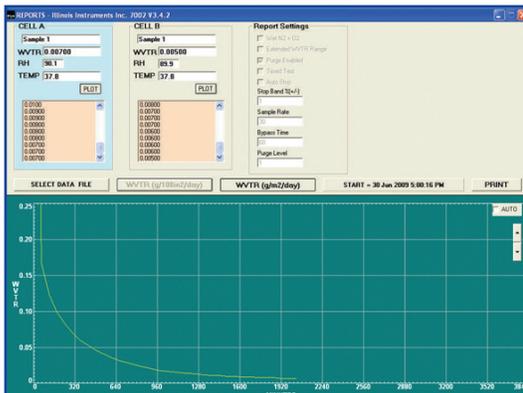
## Start up



## Set up



## Actual data

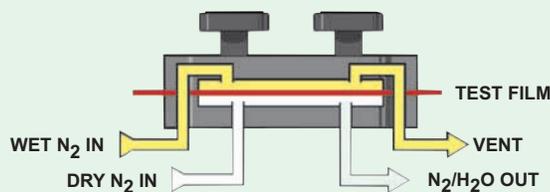


## Principle of Operation

Utilising our proprietary sensor technology to detect water vapor transmission rates, samples are clamped or attached to a diffusion chamber. Wet nitrogen is then introduced into the upper half of the chamber while a moisture-free carrier gas flows through the lower half.

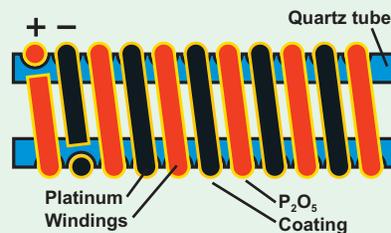
Molecules of water diffusing through the sample into the lower chamber are conveyed to the sensor by the carrier gas.

## Sample Test Chamber



This allows a direct measurement of the water vapor without using complex extrapolations. Water vapor transmission rate of the test sample is displayed as either g/m²/day or g/100in²/day.

## P₂O₅ Sensor



To achieve an absolute measure, the technology draws upon a fundamental principle of physics.

The phosphorous pentoxide (P₂O₅) moisture sensor consists of a dual platinum winding formed around a quartz tube.

The change in the resistance across the windings creates a change in the measured current. According to Faraday's Law this is directly proportional to the amount of moisture in the gas stream.

## 7000 Series - Water Vapor Permeation Analyzers

Systech Illinois' range meets the requirement for the testing of any application.



Systech Illinois' 7002 Water Vapor Transmission Analyzer delivers the same high performance as the 7001 but with an extended measurement range for more demanding applications.

### Technical Specifications

#### Measurement Range

7001	Unmasked	0.002 to 10 g/m <sup>2</sup> /day
	Masked	0.02 to 70 g/m <sup>2</sup> /day
	Package	0.00001 - 0.05 g/pack
7002	Unmasked	0.002 to 70 g/m <sup>2</sup> /day
	Masked	0.02 to 1000 g/m <sup>2</sup> /day
	Package	0.00001 - 0.05 g/pack at 10 cc flow, up to 0.5 g/pack at 50 cc flow
Test Temperature Range		41°F to 122°F (5°C to 50°C)
Test RH Range		20 to 90% RH
Sample Size		50cm <sup>2</sup> , adapters available for smaller samples

#### Operating Conditions

Operating Conditions	Standard laboratory environment
Power Requirements	100-240 VAC, 50/60Hz, 840 VA (max)
Supply Pressure	1.7 bar regulated
Gas Fittings	1/8 in. Swagelok (supplied)
Enclosure	Epoxy coated heavy gauge steel
Dimensions	20.98 x 20.98 x 12 (inches)
Weight	52 lbs

#### Options

Expansion Modules 7011 (Up to 5 modules can be linked)	Available for simultaneous WVTR analysis of up to 12 samples
Environmental Chambers	For finished package testing under special conditions

Systech Illinois have over 30 years experience of providing analysis solutions for a wide range of industries. From our manufacturing plants in the U.S and UK we produce gas analyzers for industrial process industries, headspace analyzers for monitoring gas flushing of food products, and our range of permeation analyzers.

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